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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,828	02/11/2004	Robert J. Cherney	PH 7442 NP	3372

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EXAMINER

KOSACK, JOSEPH R

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 01/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/776,828	Applicant(s) CHERNEY ET AL.	
	Examiner Joseph Kosack	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 20-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/3/04 and 3/14/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-36 are pending in the instant application.

Election/Restrictions

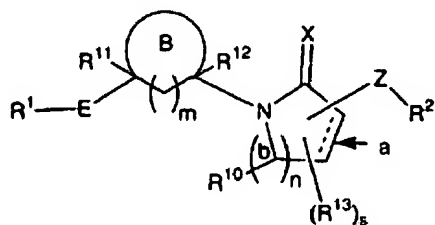
Applicant's election with traverse of Group I, claims 1-19 and an election of species of Example 147 on page 282, Table A of the specification in the reply filed on December 13, 2005 is acknowledged. Applicant's arguments have been considered, but they have not been found persuasive.

The requirement is still deemed proper and is therefore made FINAL.

Status of the Claims

Claims 1-36 are pending in the instant application. Claims 1-19 (in part), and Claims 20-36 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in the structure and element and would require separate search considerations. In addition, a reference, which anticipates one group, would not render obvious the other.

Pursuant to Applicant's election of a species, the scope of the invention will be limited to the following substitutions of the base structure



where:

- B will represent cyclohexyl with substitutions as defined;

- a will be a single bond;
- R¹ will be phenyl with substitutions as defined;
- n will be 1;
- Z will be -NH-;
- R² will be a 5-10 membered heteroaryl system containing 1-4 heteroatoms selected from N, O, and S, substituted as defined;
- E, R¹, R¹¹, and all other substituents will be as defined.

As a result of the election and the corresponding scope of the invention defined supra, the remaining subject matter of Claims 1-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to non-elected inventions. The withdrawn compounds contain varying functional groups such as pyrimidinyl, piperidinyl, imidazolyl, pyrrolidinyl, etc, which are chemically recognized to differ in structure and function. This recognized chemical diversity of the functional groups can be seen by the various classification of these functional groups in the U.S. classification system, i.e. class 544 subclass 244(+) (diazines), class 546 subclass 184(+) (piperidines), 546 subclass 249(+) (pyridines), etc. Therefore the subject matter which are withdrawn from consideration as being non-elected subject matter differ materially in structure and composition and have been restricted properly a reference which anticipated but the elected subject matter would not even render obvious the withdrawn subject matter and the fields of search are not co-extensive.

Priority

The claim to priority of US Serial Number 60/446,850 filed on February 12, 2003 has been acknowledged in the instant application.

Information Disclosure Statement

The Information Disclosure Statements filed on June 3, 2004 and March 14, 2005 have been considered fully by the examiner.

Claim Objections

Claims 1-19 are objected to for containing elected and non-elected subject matter. The elected subject matter have been identified supra.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

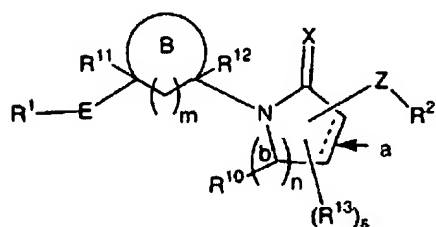
This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-19 rejected under 35 U.S.C. 103(a) as being unpatentable over Ewing et al. (WO 99/37304 A1).

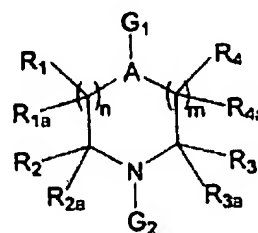
The instant application cites a compound of the base structure



where: B is cyclohexyl with substitutions as defined;

a is a single bond; R¹ is phenyl with substitutions as defined; n is 1; Z is -NH-; R² is a 5-10 membered heteroaryl system containing 1-4 heteroatoms selected from N, O, and S, substituted as defined; E, R¹, R¹¹, and all other substituents are as defined.

Determination of the scope and content of the prior art (MPEP §2141.01)



Ewing et al. teach a lactam with the base formula:

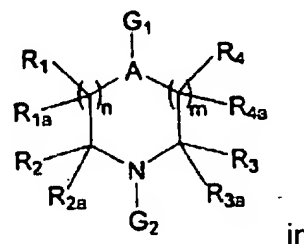
with

substitutions as defined. See page 2, line 18.

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Ascertainment of the difference between the prior art and the claims (MPEP§2141.02)

Ewing et al. do not teach specifically the compounds of the instant invention.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

Ewing et al. teach generally lactams with the base formula:

which n is 0; R₂ and R_{2a} combine to make =O or =S; G₂ is L₂-Cy₂ where L₂ is absent and Cy₂ is optionally substituted cycloalkyl; A is CH; G₁ is L₁-Cy₁ where L₁ is NR⁵ where R⁵ is hydrogen and Cy¹ is optionally substituted heteroaryl; m is 1; R₃, R_{3a}, R₄, and R_{4a} are as defined.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to follow the synthetic scheme of Ewing et al. and make the claimed invention with a reasonable expectation of success. The motivation to do so is provided by Ewing et al. Ewing et al. teach the use of the synthesized compounds to inhibit Factor Xa to treat disorders related to blood coagulation in mammals. See page 1, line 11 through page 2, line 7; and page 5, lines 2-4.

Thus, the claimed invention as a whole was *prima facie* obviousness over the combined teachings of the prior art.

Conclusion

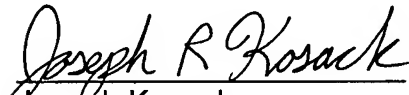
Claims 1-19 are rejected. Claims 1-19 are objected to.

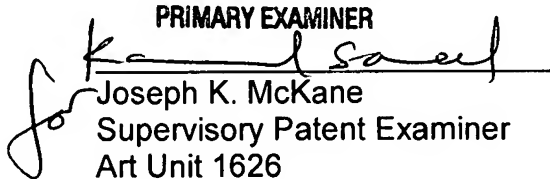
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Kosack whose telephone number is (571)-272-5575. The examiner can normally be reached on M-F 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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Art Unit 1626

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